Individual Safety Report

3601199-7-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
alth professionals of adverse
nts and product problems

CDER ODE

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Form Approved: OMB No. 0910-0291 Expires:12/31/04
See OMB statement on reverse

FDA Use Only H Pad

Triage unit sequence # 131517

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
00-84 In confidence	or Date of birth: 05/30/1943	☑ female ☐ male	135 lbs or ___ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death (mo-day-yr)
- ☐ life-threatening
- ☑ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mo-day-yr): 07/02/2000

4. Date of this report (mo-day-yr): 10/03/2000

5. Describe event or problem

On day of admission, pt. developed substernal chest pain radiating to her back, worsening pain of (L) shoulder, SOB. Pt. was found to be tachycardic and tachypneic, her blood sugar was greater than 500. Pt. was dehydrated.

Liver function tests were elevated.

Tylenol D/C'ed and pt. instructed to avoid Tylenol.

Liver function tests performed, 7/2/00: Tylenol level <10.0 ug/mL.

6. Relevant tests/laboratory data, including dates

AST = 926 on 7/2/00,
ALT = 1348 on 7/2/00
TBIL = 2.3 on 7/2/00.

DSS

TBIL = 1.2 on 7/5/00.
ALT = 969 on 7/5/00
AST = 695 on 7/5/00.

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7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction etc.)

IDDM, Hypothyroidism, Vitiligo, Seizure disorder, mild mitral stenosis

CTV131517

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Tylenol (Extra Strength)
#2

2. Dose, frequency & route used
#1 8-10 tabs / Day
#2

3. Therapy dates (if unknown, give duration) (from/to (or best estimate))
#1 PTA
#2

4. Diagnosis for use (indication)
#1 (L) Shoulder Pain
#2

5. Event abated after use stopped or dose reduced
#1 ☑ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1 unknown
#2

7. Exp. date (if known)
#1 unknown
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☑ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)
Phenobarbital, Synthroid, NPH Insulin, Celebrex

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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MEDWATCH CTU

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other:

5. Expiration date (mo-day-yr)

6.
model # ___
catalog # ___
serial # ___
lot # ___
other # ___

7. If implanted, give date (mo-day-yr)

8. If explanted, give date (mo-day-yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on (mo-day-yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone [redacted]

2. Health professional? ☒ yes ☐ no

3. Occupation: Pharmacist

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☒

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787
or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.